

234 CMR 3.00: ADMINISTRATION OF GENERAL ANESTHESIA, DEEP SEDATION, CONSCIOUS SEDATION, AND NITROUS OXIDE-OXYGEN SEDATION

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3.01: Scope

- (1) Effective April 1, 1988, no licensed dentist shall administer general anesthesia, deep sedation, conscious sedation, and/or nitrous oxide-oxygen sedation, unless such dentist has been issued an anesthesia administration permit by the Massachusetts Board of Registration in Dentistry (the Board).
- (2) Effective April 1, 1988, administration permit holders may only administer general anesthesia, deep sedation, conscious sedation, and/or nitrous oxide-oxygen sedation at those sites which have been issued a facility permit by the Board or in those hospital or dental school settings described in 234 CMR 3.04(2).
- (3) An anesthesia administration permit holder may administer anesthesia or sedation as authorized by his/her type of administration permit (Permit A, B, or C) at any facility which has been issued a facility permit (Permit D) by the Board.

3.02: Definitions

Conscious Sedation: Sedation in which protective reflexes are normal or minimally altered. The patient remains conscious and maintains the ability to independently maintain an airway and respond appropriately to verbal command. Conscious sedation also includes the use of other sedative agents and/or premedication in combination with nitrous oxide-oxygen.

Deep Sedation: A depressed level of consciousness, which may range to unconsciousness, from which the patient is not easily aroused. It may be accompanied by a partial or complete loss of protective reflexes, including the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command.

General Anesthesia: A controlled state of unconsciousness, accompanied by a partial or complete loss of protective reflexes, which may include inability to maintain an airway independently and to respond purposefully to physical stimulation or verbal command.

Nitrous Oxide-Oxygen Sedation: Conscious sedation accomplished solely by the use of nitrous oxide-oxygen.

3.03: Permits

A two year administration permit, category specific, to administer general anesthesia, deep sedation, conscious sedation, and/or nitrous oxide-oxygen sedation may be issued by the Board to dentists meeting the qualifications listed below. A two year facility permit may be issued by the Board to facilities meeting the qualifications listed in 234 CMR 3.03(1).

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(1) Categories of Permits.

(a) Administration Permits. An anesthesia administration permit A, B, or C must be obtained by every dentist who administers general anesthesia, deep sedation, conscious sedation, and/or nitrous-oxide oxygen sedation. The requirement of obtaining an administration permit shall not apply to those dentists working with a qualified anesthesiologist (M.D., D.O., or Dental Anesthesiologist). The requirement of obtaining a facility permit, however, as set forth in 234 CMR 3.03(1)(b), shall apply to the facilities where any such dentist works with the anesthesiologist. In addition to the educational qualifications set forth below regarding administration permits A, B and C, all dentists applying for any type of administration permit must successfully complete an anesthesia administration evaluation conducted by the Board or its agent, as set forth in 234 CMR 3.04(1).

1. PERMIT A - Administration of General Anesthesia, Deep Sedation, Conscious Sedation, and/or Nitrous-Oxide Oxygen Sedation: Educational Qualifications. Educational qualifications for the issuance of Permit A include documentation of:

- a. successful completion of a minimum of one year advanced training in anesthesiology beyond the dental school level;
- b. having met the educational requirements for certification by the American Board of Oral and Maxillofacial Surgery; or
- c. certification as a Fellow in Anesthesia by the American Dental Society of Anesthesiology.

2. PERMIT B - Administration of Conscious Sedation Only: Educational Qualifications. Documentation of having successfully completed a course which conforms to the American Dental Association Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, Parts 1 and 2.

3. PERMIT C - Administration of Nitrous Oxide-Oxygen Sedation Only: Educational Qualifications. Documentation of having successfully completed a course which conforms to the American Dental Association Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, Parts 1 and 2.

(b) Facility Permits.

1. PERMIT D - Facility Permit for General Anesthesia, Deep Sedation, Conscious Sedation, and/or Nitrous Oxide-Oxygen Sedation Qualifications. A facility permit D must be obtained for every office site in which general anesthesia, deep sedation, conscious sedation, and/or nitrous oxide-oxygen sedation is administered. Facility permits are also required for the offices of those dentists who work with a qualified anesthesiologist (M.D., D.O., or Dental Anesthesiologist).

(c) Temporary Permits for New Applicants.

1. Temporary Administration Permit. For dentists who qualify for an administration permit, a temporary permit may be granted by the Board. The granting of such temporary permit shall be based upon an evaluation of the applicant's qualifications as stated in the application and pending the applicant's successful completion of an anesthesia administration evaluation conducted by the Board or its agent.

2. Temporary Facility Permit. For sites which qualify for a facility permit, a temporary permit may be granted by the Board. The granting of such temporary permit shall be based upon an evaluation of the facility, its equipment and personnel as stated in the application and pending a satisfactory on-site facility inspection conducted by the Board or its agent.

3. Renewal. All administration and facility permits must be renewed every two years.

3.04: Anesthesia Administration Evaluations and On-Site Facility Inspections

Anesthesia administration evaluations and on-site facility inspections shall be conducted by at least one evaluator appointed by the Board upon recommendation of the Anesthesia Review Committee. If the results of the evaluation or inspection are deemed unsatisfactory, a second evaluation or inspection may be conducted, within a reasonable time, by a different evaluator upon written request of the applicant.

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(1) Approval for Administration Permits A, B, and C. Evaluations for anesthesia administration permits shall include observing actual dental treatment under general anesthesia, deep sedation, conscious sedation, and/or nitrous-oxide oxygen sedation, as appropriate to the type of permit applied for by the applicant. The office personnel must also demonstrate cardio-pulmonary resuscitation (CPR) and an emergency drill as well as show documentation of scheduled office drills.

(2) Approval for Facility Permit D. Approval shall require an on-site inspection of the facility, drugs and equipment, and personnel utilized in the administration of anesthesia. Facility requirements are listed in 234 CMR 3.05. Facility permits are not applicable to those hospital and/or dental school settings which have been approved by the Joint Commission on Accreditation of Hospitals or the Commission on Accreditation of the Council on Education of the American Dental Association. Private dental offices of dentists practicing within hospital or dental school facilities, however, are subject to 234 CMR 3.00.

3.05: Facility Requirements and Patient Monitoring Procedures

Every facility utilized by a dentist with an administration permit or by a dentist with no permit who is working with a qualified anesthesiologist must be properly equipped for the type of anesthesia or sedation being administered and staffed with a supervised team of auxiliary personnel capable of appropriately managing procedures and emergencies incident thereto. The facility design shall be such that there is access for emergency and transport equipment. Adequacy of the facility, equipment, and competence of the personnel shall be determined as outlined in 234 CMR 3.05.

(1) Drugs and Equipment Required for Administration of General Anesthesia, Deep Sedation, Conscious Sedation, and/or Nitrous Oxide-Oxygen Sedation. A facility which administers general anesthesia, deep sedation, conscious sedation and/or nitrous oxide-oxygen sedation must be equipped with the following drugs and equipment:

- (a) suction;
- (b) monitoring equipment (including stethoscope and sphygmomanometer);
- (c) equipment capable of delivering oxygen under positive pressure;
- (d) gas delivery machines must have an oxygen fail-safe system, adequate waste gas scavenging, and shall be checked and calibrated periodically;
- (e) a protocol for management of emergencies shall be developed and emergency drills must be carried out and documented;
- (f) all emergency equipment and drugs must be maintained on a scheduled basis;
- (g) an adequate supervised recovery area must be available;
- (h) epinephrine;
- (i) an antihistamine;
- (j) an anticonvulsant;
- (k) vasodilator (e.g. nitroglycerine);
- (l) an antihypoglycemic agent;
- (m) a bronchodilator;
- (n) a corticosteroid;
- (o) vasopressor;
- (p) equipment for the insertion and maintenance of an intravenous infusions (not required for facilities administering nitrous oxide-oxygen only); and
- (q) a pulse oximeter (effective 1/1/91) (not required for facilities administering nitrous oxide-oxygen only).

(2) Additional Drugs and Equipment Required for Administration of General Anesthesia and/or Deep Sedation. The following drugs and equipment must also be available in a facility which administers general anesthesia and/or deep sedation:

- (a) a narcotic antagonist;
- (b) a muscle relaxant;
- (c) atropine;
- (d) lidocaine;
- (e) sodium bicarbonate;

## 3.05: continued

- (f) dantrolene sodium (required if a halogenated anesthesia agent (e.g. halothane, enflurane, isoflurane) is used or depolarizing skeletal muscle relaxants (e.g. succinylcholine) are administered);
- (g) EKG monitor and defibrillator; and
- (h) endotracheal tubes and laryngoscope.

(3) Patient Monitoring. The following procedures must be followed by administration permit holders:

(a) Medical History. An appropriate medical history shall be recorded on the patient's chart prior to the administration of general anesthesia, deep sedation, conscious sedation, and/or nitrous oxide-oxygen sedation.

(b) Monitoring and Recording of Vital Signs.

1. General Anesthesia and Deep Sedation. Monitoring and recording of vital signs including blood pressure, respiration, and heart rate must be done for all patients administered general anesthesia and deep sedation. In addition, an EKG monitor and a pulse oximeter (effective 1/1/91) must be used. The temperature of children administered general anesthesia must be monitored.

2. Conscious Sedation. Monitoring and recording of vital signs including blood pressure, respiration, and heart rate must be done for all patients administered conscious sedation. In addition, a pulse oximeter must be used (effective 1/1/91).

3. Nitrous Oxide - Oxygen Sedation. Baseline monitoring and recording of vital signs, including blood pressure, respiration, and heart rate must be done for all patients administered nitrous oxide-oxygen sedation whenever possible. Intraoperative monitoring requires observation of appropriate physiologic parameters.

(c) The Anesthesia Chart. For patients administered general anesthesia, deep sedation, conscious sedation, and/or nitrous oxide-oxygen sedation, the anesthesia chart shall contain documentation that vital signs have been recorded, and that the responsiveness of the patient was checked at specific intervals, including the recovery period. The chart must also record the duration of the procedure and agents administered. A note of the patient's condition upon discharge must also be recorded.

(d) Utilizing an Anesthesiologist. When a qualified anesthesiologist (M.D., D.O., or Dental Anesthesiologist) is utilized, such individual must remain on the dental facility premises until any patient administered general anesthesia, deep sedation, and/or conscious sedation regains full consciousness.

(e) Personnel. The following personnel requirements must be met in all facilities administering general anesthesia, deep sedation, conscious sedation, and/or nitrous oxide-oxygen sedation:

1. General Anesthesia and Deep Sedation. For general anesthesia and/or deep sedation, at least three appropriately trained individuals are required:

- a. the operating dentist, who directs the general anesthesia and/or deep sedation;
- b. A person responsible for observing and monitoring the patient. If this person is an appropriately trained professional, he or she may direct and/or administer the general anesthesia and/or deep sedation; and
- c. A person assisting the operating dentist. The person responsible for administering the anesthesia must remain on the premises until the patient regains full consciousness.

2. Conscious Sedation and/or Nitrous Oxide-Oxygen Sedation. For conscious sedation and/or nitrous oxide-oxygen sedation, at least two appropriately trained individuals are required:

- a. the operating dentist, who directs the conscious sedation and/or nitrous oxide-oxygen sedation; and
- b. an assistant trained to monitor appropriate physiologic parameters.

(f) Certification in Cardio-Pulmonary Resuscitation (CPR). All personnel involved in the administration of general anesthesia, deep sedation, conscious sedation and/or nitrous oxide-oxygen sedation must be currently certified in cardio-pulmonary resuscitation (CPR).

3.06: Anesthesia Review Committee

(1) Members. The Board shall appoint an Anesthesia Review Committee, such committee to consist of at least five individuals with the Chairman of the Board's Committee on Anesthesia and Sedation as a permanent member. The following members will have staggered five year terms:

- (a) At least one Diplomate of the American Board of Oral and Maxillofacial Surgery;
- (b) At least one member of the Massachusetts Dental Society of Anesthesiology who is a Fellow of the American Dental Society of Anesthesiology;
- (c) At least one member of the Anesthesia Committee of the Massachusetts Society of Oral and Maxillofacial Surgeons; and
- (d) At least one diplomate of the American Board of Pediatric Dentistry.

(2) Duties and Responsibilities. The Anesthesia Review Committee shall have the duty and responsibility to:

- (a) review applications;
- (b) make recommendations to the Board of individuals (*i.e.* evaluators) to conduct administration evaluations and on-site facility inspections;
- (c) evaluate results of administration evaluations and on-site facility inspections;
- (d) recommend to the Board the granting of administration and facility permits; and
- (e) periodically review qualifications for the issuance of administration and facility permits.

(3) Qualifications of Evaluators. All dentists performing administration evaluations and on-site facility inspections shall meet the educational requirements for Fellowship of the American Dental Society of Anesthesiology.

(4) Credentials. The Board may, at its discretion, accept the results of an administration evaluation or on-site facility inspection performed by the Anesthesia Committee of the Massachusetts Society of Oral and Maxillofacial surgeons or other appropriate organization that meets the requirements of the Anesthesia Review Committee of the Board as fulfillment of the Board's administration evaluation or on-site facility inspection requirement.

(5) Payment to Evaluators. Evaluators will be compensated by the Commonwealth of Massachusetts through the Division of Registration.

(6) Terms of Appointment. Of those persons first appointed by the Board as members of the Anesthesia Review Committee, one member shall be appointed for a term to expire in January, 1989, one member shall be appointed to a term to expire in 1990, one member shall be appointed to a term to expire in 1991, one member shall be appointed in a term to expire in 1992 and one member shall be appointed to a term to expire in 1993.

3.07: Adverse Occurrences

A dentist who holds an administration permit issued pursuant to 234 CMR 3.00, shall report to the Board any anesthesia, deep sedation, conscious sedation and/or nitrous oxide-oxygen sedation related mortality which occurs during or as a result of treatment provided by the administration permit holder within 48 hours of the occurrence of any such mortality. Any morbidity which may result in permanent physical or mental injury as a result of the administration of general anesthetic agents, sedative agents or nitrous oxide-oxygen analgesia shall be reported to the Board by the administration permit holder providing such treatment within 30 days of the occurrence of any such morbidity.

3.08: Penalty for Non-compliance

Non-compliance with 234 CMR 3.00 shall subject a licensee's administration permit, facility permit and/or dental license to disciplinary action by the Board.

3.09: Scope of Permit L-Local Anesthesia Permit for Dental Hygienists

(1) No licensed dental hygienist shall administer local anesthesia, unless such dental hygienist has been issued a Permit L-Local Anesthesia Permit by the Board.

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(2) A dental hygienist who holds a Permit L-Local Anesthesia permit may administer such anesthesia only under the direct supervision of a dentist licensed in Massachusetts.

### 3.10: Definition of Direct Supervision

Direct Supervision means the dentist is in the dental office, personally diagnoses the condition to be treated, personally authorizes the procedure(s)/duty(ies), remains physically present within the confines of the dental facility while the procedure(s)/duty(ies) are being performed, and examines the patient before his/her dismissal.

### 3.11: Qualifications of Dental Hygienists for Permit L

(1) A two-year administration permit to administer local anesthesia may be issued by the Board to dental hygienists meeting the qualifications in 234 CMR 3.11(2)(a) and (b).

(2) Permit L to Administer Local Anesthesia. A dental hygienist seeking a permit to administer local anesthesia must meet all of the following qualifications:

- (a) Be licensed as a dental hygienist in Massachusetts; and
- (b) Provide the Board with documentation demonstrating:
  - 1. Current certification in Basic Life Support and/or CPR;
  - 2. Successful completion of a training program or course of study in a formal program in the administration of local anesthesia, which shall be a minimum of 35 hours of instruction, including no less than 12 hours of clinical training, and be conducted by an educational institution accredited by the Commission on Dental Accreditation of the American Dental Association; and
  - 3. Successful completion of a written examination in the administration of local anesthesia administered by the Northeast Regional Board of Dental Examiners (NERB) or any successor agency approved by the Board.

(3) Instructors training students for certification to be certified to administer local anesthesia in Massachusetts shall be licensed to practice dentistry or dental hygiene in this state.

### 3.12: Course of Study for Permit L

An applicant for a Permit L-Administration of Local Administration shall have completed a minimum of 35 hours of instruction, which must include, but is not limited to:

- (a) Medical History evaluation procedures;
- (b) Physical evaluation of the dental patient;
- (c) Pharmacology of local anesthesia and vasoconstrictors; and
- (d) Local anesthesia, didactic and clinical courses, including the following:
  - 1. Anatomy of head, neck, and oral cavity as it relates to administering local anesthetic agents;
  - 2. Indications and contraindications for administration of local anesthesia;
  - 3. Selection and preparation of the armamentaria and record keeping for administering various local agents;
  - 4. Medical and legal management of complications;
  - 5. Recognition and management of post-injection complications;
  - 6. Proper infection control techniques with regard to local anesthesia and proper disposal of sharps;
  - 7. Methods of administering local anesthetic agents with emphasis on technique and minimum effective dosage; and
  - 8. Management of diagnosis, prevention and treatment of medical emergencies.

### 3.13: Application for and Renewal of Permit L

(1) Application for Permit L-Local Anesthesia Permits. Application for a local anesthesia permit shall be on forms provided by the Board and shall be accompanied by:

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- (a) The permit fee, to be determined annually by the Secretary of Administration and Finance, made payable by check to the Commonwealth of Massachusetts; and
- (b) Documentation of the following:

- 1. Current Basic Life Support (BLS) and/or CPR certification;
- 2. Successful completion of a training program or course of study in a formal program in the administration of local anesthesia in accordance with 234 CMR 3.12 and accredited by the American Dental Association;

Completion of the training program in the administration of local anesthesia shall be successfully completed no earlier than two years preceding the date of application of Permit L.

- 3. Successful completion of a written examination in the administration of local anesthesia administered by the Northeast Regional Board of Dental Examiners (NERB) or any successor agency approved by the Board.

(2) Application for Permit L by Credentials. Application for a local anesthesia permit by a dental hygienist qualified in another jurisdiction by virtue of successful completion of an examination to administer local anesthesia shall be accompanied by:

- (a) The permit fee, to be determined annually by the Board, made payable by check to the Commonwealth of Massachusetts; and
- (b) Documentation of the following:

- 1. Current Basic Life Support (BLS) and/or CPR certification;
- 2. Documentation of successful completion of a training program or course of study in a formal program in the administration of local anesthesia accredited by the American Dental Association and equivalent to the course of study described in 234 CMR 3.12; and
- 3. A letter from the dentist who directly supervised the hygienist attesting to the hygienist's experience in administering local anesthesia within the previous two years.

(3) Renewal of Anesthesia Permits. A Permit to administer Local Anesthesia shall be renewed biennially, at the same time the applicant's license to practice dental hygiene is renewed. The application for renewal of Permit L shall be accompanied by:

- (a) The permit fee, to be determined annually by the Board, made payable by check to the Commonwealth of Massachusetts; and
- (b) Documentation of the following: Current Basic Life Support (BLS) and/or CPR certification.

3.14 Recording of Anesthesia

(1) The dental hygienist shall obtain the local anesthesia only from the licensed dentist who is exercising direct supervision of the dental hygienist administering the local anesthesia.

(2) The dental hygienist shall sign and document in the patient record the date, type and amount of local anesthesia obtained from the supervising dentist.

(3) Upon completion of the treatment, any unused portion of the local anesthesia and armamentarium shall be returned to the supervising dentist and disposed of according to the Center for Disease Control (CDC) Guidelines.

REGULATORY AUTHORITY

234 CMR 3.00: M.G.L. c. 112, § 43.

NON-TEXT PAGE